June 9, 2022

ILOODA Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St. Ste 610
Houston, Texas 77054

Re: K211000
Trade/Device Name: Acutron
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 4, 2022
Received: April 11, 2022

Dear Dave Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211000

Device Name
ACUTRON

Indications for Use *(Describe)*

ACUTRON is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K211000

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date 510k summary prepared: July 6, 2022

I. SUBMITTER

Submitter's Name :	Ilooda Co.,Ltd
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DEVICE	
Trade/proprietary name:	ACUTRON
Common or Usual Name:	Micro-needle RF system
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI)
Regulatory Class:	Class II
Prescription Use.	

PREDICATE DEVICE

Device Manufacturer:	ILOODA CO.,LTD
Device Name:	Secret ^{RF} Smartcure Applicator
510(k) Number:	K182355
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI, OUH)
Regulatory Class:	Class II

REFERENCE DEVICE

Device Manufacturer:	ILOODA CO., LTD
Trade/proprietary name:	Secret ^{RF}
Common or Usual Name:	Micro-needle Fractional RF
510K number:	K170325
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI, OUH)
Regulatory Class:	Class II

These devices have not been subject to a design-related recall.

II. DEVICE DESCRIPTION

ACUTRON is High Frequency(=Radio Frequency, RF) includes the system main body, a handpieces with single-use micro-needle type electrodes, footswitch and an LCD touch screen control panel.

The RF energy is delivered to the target tissue using a handpiece and disposable tip(micro needle electrode tip), the tip being placed in light contact with the epidermis and the handpiece being held at right angles to the target tissue. As the RF energy passes through the skin, it generates an electro thermal reaction, which is capable of coagulating the tissue.

Using the micro needle tip, the ACUTRON creates heat within the target dermal tissue via micro-needles inserted from the tip.

The ACUTRON is consists of ;

1) Main unit
2) Smartcure handpiece(FDA cleared K182355)
3) Monopolar type micro-needle electrodes(FDA cleared K182355)

IV. INDICATIONS FOR USE:

ACUTRON is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

		Proposed Device	**Predicate Device**	**Remark**
		ACUTRON (K211000)	**Secret RF Smartcure applicator (K182355)**	
Indications for use		ACUTRON is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	Secret RF Smartcure applicator is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis	
Handpieces				Same
Handpiece material		Aluminum	Aluminum	Same
Patient return electrode		All-in-one connection with Patient plate connector. The handpiece and the counter plate connector are connected to one connector of the main body and do not affect the safety or effectiveness performance.	The electrode handpiece and the patient plate are separate.	Same
Frequency		2MHz ± 10%	2MHz ± 10%	Same
Output Power		0.1W ~ 45W at 500Ω	0.1W ~ 45W at 500Ω	Same
Treatment time		10~15min (recommended)	10~15min (recommended)	Same
With Connected Needle electrodes		MTR-AC series		
		MTR-AC-01, MTR-AC-04, MTR-AC-27G		Same
Needle material	Body	PC(Polycarbonate)	PC(Polycarbonate)	Same
	needle	Stainless Steel 304 + Perylene coating	Stainless Steel 304 + Perylene coating	Same

Electrode Needle Specification								
Model name		**ACUTRON (K211000)**			**Secret RF Smartcure applicator (K182355)**			
510(k)number		K211000			K182355			
Model name of electrode		MTR AC-27G	MTR AC-01	MTR AC-04	MTR AC-27G	MTR AC-01	MTR AC-04	Same
Configuration		Body + Needle			Body + Needle			Same
Physical SPEC.	Total length (mm)	40	20	20	40	20	20	Same
	Needle(tip) Diameter	ø0.4	Ø0.25	Ø0.25	ø0.4	Ø0.25	Ø0.25	Same
	Needle(tip) Length(mm)	3.0	2.5	1.5	3.0	2.5	1.5	Same
	Needle(tip) Unit	1	1	4	1	1	4	Same
Patient Contacting Materials	Body (indirect)	Polycarbonate			Polycarbonate			Same
	Needle	Stainless steel 304 + Perylene coating			Stainless steel 304 + Perylene coating			
Output power		Max 45W			Max 45W			Same
Type and operation mode		Monopolar (Normal mode)			Monopolar (SC mode)			Same
Single Use		Single use			Single use			Same
Sterilization method		E.O gas			E.O gas			Same

	Proposed device	**Reference device**	**Remark**
Model name	ACUTRON	Secret ^{RF}	
Manufacturer	ILOODA CO.,LTD	ILOODA CO.,LTD	
510(k)number	K211000	K170325	
Intended use	ACUTRON is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	SECRET RF is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis	Same
Rated voltage	100-240V~, 50/60Hz	100-240V, 50/60Hz	
User interface	Color touch Panel	Color touch Panel	Same
Dimension(mm)	Main unit : 274(W)x187(D)x291(H)	Main unit : 180(W)x460(D)x1100(H)	
Delivery system	Monopolar handpieces + Micro needle electrodes	Monopolar handpiece + Micro needle electrodes	Same

Mode of operation	Monopolar mode (Normal mode)	Monopolar (SC mode)	Same monopolar
Method of activation	Footswitch	Footswitch	Same
Output energy type	High frequency	High frequency	Same
Frequency	2MHz ± 10%	2MHz ± 10%	Same
Max power	Max 45W at 500Ω	Max 45W at 500Ω	Same

ACUTRON has the same technical specifications and same indications for use as those of the predicate device and the reference device.

The main differences are:

- Change in the dimension of the device
- Change in GUI design

1. Main unit(RF console)

   ACUTRON has been specifically designed for the Secret RF Smartcure applicator handpieces, the predicate device (K182355) and identical operating specifications compared with the Secret RF system, the reference device (K170325). Electrical and mechanical safety and performance of ACUTRON electrosurgical system have been verified according to international standards.

2. Handpiece

   ACUTRON handpieces include the identical handpiece needles cleared for the predicate device, Smartcure Applicator (K182355). Therefore, ACUTRON handpieces are subject to the same biocompatibility, sterilization, cleaning, packaging, shelf-life performance validation testing for the Smartcure Applicator handpieces, the predicate device, K182355.

3. GUI Design

   ACUTRON has been specifically designed for the Secret RF Smartcure applicator handpieces, the predicate device(K182355). The normal mode is identical to the SC mode of the Secret RF system , the reference device(K170325).

VI. PERFORMANCE DATA

Design verification process were performed following risk assessment to verify that no new questions of safety and effectiveness have been raised due to the modifications

introduced.

Biocompatibility testing:

The patient contact components and materials are identical to the predicate device. The biocompatibility is being leveraged from the predicate device.

Non Clinical testing:

IEC 60601-1: 2005, AMD 1: 2012 Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance. The requirements of specified standards were fulfilled.

IEC 60601-1-2: 2014 Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance (collateral standards: electromagnetic compatibility.

IEC 60601-2-2: 2017 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high-frequency surgical equipment and high-frequency surgical accessories.

Animal testing:

Ex-vivo histology testing for ACUTRON handpieces is being leveraged from the Smartcure Applicator handpieces, the predicate device.

VII. CONCLUSIONS

There are no significant differences between ACUTRON and the predicate device and the reference device.

The proposed device does not raise any additional questions regarding safety and effectiveness. ACUTRON has the same indication of use and shares the same technological characteristics as the predicate devices.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, it is the opinion of Ilooda Co, Ltd. that ACUTRON is substantially equivalent in comparison with the predicate device and the reference device as described herein.